MARCH 2022

IOWA BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

Non-electronic Prescriptions – Reminder of Requirements

Iowa requires prescriptions to be transmitted to pharmacies electronically, and at least 37 states will mandate e-prescribing in some form within the next few years. However, there are many instances whereby a pharmacist may be presented with a non-electronic prescription. As non-electronic prescriptions become less common, it is important to ensure that the prescriptions contain all the elements required by Iowa Code and Iowa Board of Pharmacy rule.

657 Iowa Administrative Code (IAC) 8.19(1) provides the required elements of a valid prescription. For written (ie, hard copy), electronic, or facsimile prescriptions, the following information must be included:

- The date the prescription was issued by the prescriber
- The name and address of the patient (possible exceptions: epinephrine auto-injectors, opioid antagonists, or expedited partner therapy)
- The name, strength, and quantity of the drug or device prescribed
- The name and address of the prescriber
- Drug Enforcement Administration (DEA) number of the prescriber (for controlled substances (CS) only)
- The written or electronic signature of the prescriber (written and facsimile CS prescriptions must be manually signed)

In addition to the above, facsimile prescriptions must also include:

- The identification of the facsimile machine used to transmit the prescription to the pharmacy
- The time and date of transmission of the prescription

- The name, address, telephone number, and facsimile number of the pharmacy to which the prescription is being transmitted

Remember that if a prescriber authorizes an agent to transmit prescriptions to the pharmacy (oral, facsimile, electronic), the prescription must identify the first and last names and title of the agent.

FDA Warning on Dissolvable Buprenorphine and Dental Problems

Buprenorphine is a medication used to treat opioid use disorder and pain. Food and Drug Administration (FDA) is now warning users and practitioners about the risk of dental problems linked with certain forms of buprenorphine. The drug products associated with dental problems are dissolvable tablets administered under the tongue and a film placed inside the cheek, with or without naloxone.

Patient counseling is a crucial step to reduce adverse reactions and support medication adherence. When dispensing these buprenorphine products, pharmacists should include the following points:

- After the medicine has fully dissolved, take a large sip of water, swish, and swallow.
- Wait at least one hour after use before brushing your teeth to avoid damage.
- Speak with a dentist to create a prevention strategy and regularly attend dental check-ups. Tell your dentist about all medications you take.
- Notify both your health care professional and your dentist immediately if you experience any problems with your teeth or gums.

FDA will require a new warning about the risk of dental problems in prescribing and patient information. If patients experience dental problems, they are encouraged to fill out an adverse event report.

Get to Know Your Pharmacy Board Members – Gayle Mayer

The March Board member highlighted is Gayle Mayer, RPh, FASHP. Gayle is the vice chairperson of the Board and is a retired hospital pharmacist with community pharmacy experience. Gayle previously served on the Iowa Pharmacy Association Board, which asked her to consider serving on the Board of Pharmacy. One misconception Gayle thinks people may have about the Board is that it is primarily punitive. Rather, the Board protects the public's health by guiding its licensees through timely communications and inspections to ensure that licensees provide maximum value to the citizens of Iowa. Gayle commends the compliance officers for the work they do through the inspection process and the role they play to carry out the mission of the Board. If she could do anything for one day, she would go on adventures with family, especially her grandkids. Over time, she has learned to enjoy and appreciate life and whatever each day brings. Her favorite place to be is her own beach, with friends and family visiting. When asked about her favorite ice

cream flavor, she could not pick just one! She loves all ice cream. In her free time, and weather permitting, Gayle enjoys collecting beach glass and creating jewelry from it. She enjoys walking and biking, boating, reading, and working on puzzles. She cannot live without her grandkids.

Shipping Compounded Prescriptions Outside the State of Iowa? – Reports Due by April 1, 2022

In September 2021, the Board authorized the executive director to sign a memorandum of understanding (MOU) with FDA. The purpose of the MOU is to ensure that states are providing adequate oversight of pharmacy compounders who are compounding human prescription drugs and shipping those products to patients residing in other states.

To comply with the MOU, the Board promulgated 657 IAC 20.24(1), which states: "No later than April 1, 2022, and annually thereafter, each licensed pharmacy located in Iowa that distributed compounded preparations for human use interstate in the previous calendar year shall report compounding data to the NABP information sharing network."

The National Association of Boards of Pharmacy® (NABP®) has developed the information sharing network (ISN) to assist board of pharmacy compliance with the MOU. Iowa pharmacies that distributed compounded preparations for human use to patients in other states during the previous calendar year must enter compounding and complaint information into the ISN. Iowa pharmacies that did not distribute any compounded preparations for human use to patients in other states during the previous calendar year do not need to report information to the ISN.

Data are entered by compounding pharmacies via their NABP business e-Profile. Data on interstate distribution of compounded products must be submitted by April 1, 2022, and annually thereafter.

Visit NABP for more information.

Statewide Protocols

Training, education, and reporting information for statewide protocols is now located solely in the protocol documents. Iowa Code Section 155A.46 allows the Board to develop certain statewide protocols (SWPs). Current Board-authorized SWPs include nicotine-replacement tobacco cessation, naloxone, point-of-care testing and treatment for Group A streptococcal pharyngitis and influenza, and immunizations, including emergency vaccinations for public health emergencies such as the coronavirus disease 2019. Section 155A.46 requires pharmacist training and education, as well as appropriate reporting and record retention. Products dispensed pursuant to SWPs must be labeled with the pharmacist's name as the authorizing practitioner. **To reiterate, the pharmacist who is assessing a patient under a Board-authorized statewide protocol and determining that the medication or vaccination is appropriate for the patient is the ordering practitioner and should be identified as such on the resulting prescription.** Detailed information on these requirements can be found in the statewide protocol documents.

Technician Trainee Renewal/Reactivation Update

Effective January 19, 2022, technician trainees may renew or reactivate their registration when, due to exceptional circumstances, they were unable to attain national pharmacy technician certification during their initial year of training.

Chapter 3, "Pharmacy Technicians," of 657 IAC now includes the following language:

> **3.9(3)** *Renewal.* A technician trainee who is unable to complete national certification prior to the expiration of the registration may seek renewal of the registration in exceptional circumstances. To the extent practicable, the trainee should submit an application and nonrefundable fee of $20 for technician trainee renewal, on forms provided by the board, at least 30 days prior to the expiration of the registration.
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> **3.9(4)** *Reactivation.* A technician trainee who was previously registered and left the practice of pharmacy prior to obtaining national certification may seek reactivation of the registration. The individual shall submit an application and nonrefundable fee of $20 for technician trainee reactivation on forms provided by the board. Pursuant to rule 657—3.3(155A), a technician shall obtain registration prior to commencing employment as a technician trainee in an Iowa pharmacy.

The Board still expects that most technicians will successfully attain national certification within the initial trainee registration year. Exceptional circumstances will be considered on a case-by-case basis to determine if renewal or reactivation of the registration is appropriate. Technician trainees who seek renewal or reactivation of their registration must have confirmation by the Board that their registration status is current prior to continuing or commencing pharmacy practice as a technician.

Interim Pharmacist-in-Charge – New Option for Pharmacies

Effective January 19, 2022, pharmacies have the option to designate an interim pharmacist-in-charge (PIC) when the permanent PIC is out of the pharmacy on an extended leave of absence (such as medical or maternity leave) but is not officially vacating the position (ie, will be returning at the end of the leave of absence). In these situations, a pharmacy may submit to the Board an "Interim PIC Notification" form. This provides a contact for the Board during the permanent PIC's extended leave. Like a temporary PIC change notification, this serves as a notice to the Board but does not require a pharmacy license change application or fee. The interim PIC can serve up to 120 days while still maintaining the permanent PIC on the pharmacy license. However, if the permanent PIC is not able to return to duty within 120 days, the pharmacy must either identify a new permanent PIC (notifying the Board via a PIC change application and fee) or identify a temporary PIC (notifying the Board via a Temporary PIC Change Notification form).

Pharmacists Required to Report Serious Adverse Events to FAERS Following Medication Administration

FAERS is FDA's Adverse Event Reporting System. Under FDA's current reporting requirements, pharmacists are considered voluntary reporters. However, a recent change to 657 IAC rule 39.8 now mandates that Iowa pharmacists report serious complications related to medication administration to FAERS. This requirement applies when the pharmacist has directly administered medications to a patient (eg, long-acting antipsychotic injection administered at the pharmacy). This new rule took effect on January 19, 2022, and is as follows:

> **39.8(2)** *Medication administration.* A pharmacist may administer, including via delegation to authorized pharmacy personnel if so delegated or authorized by the prescriber, any medication pursuant to a prescription or medication order for an individual patient. In case of a serious complication, the pharmacist shall notify the prescriber who issued the prescription within 24 hours and shall submit a report to the United States Food and Drug Administration Adverse Event Reporting System (FAERS).

Pharmacists may report the required information using FDA Form 3500 or via electronic submission on the MedWatch website. For more information about the FAERS program, visit the MedWatch FDA safety information and FAERS website.

Board Requests Code Changes in 2022 Legislative Session

The Board has filed two bills with the Iowa Legislature to request changes to the Iowa Code during its 2022 session of the 89th General Assembly. In its pharmacy practice bill, the Board, in collaboration with the Iowa Board of Nursing, is requesting an amendment to the pharmacy and nursing practice acts to specifically authorize Iowa-licensed registered nurses to practice pursuant to a pharmacist's order in the administration of immunizations and vaccinations or in the implementation of Board-authorized statewide protocols. If signed into law, this bill will allow registered nurses to perform these functions without obtaining a separate registration from the Board of Pharmacy.

The bill also seeks to remove a code provision that requires nonresident pharmacies to provide evidence of a toll-free telephone number with access to a pharmacist for at least six days and 40 hours per week. The Board's intent is to move this requirement into Board rules to exempt situations where the pharmacy is not directly dispensing medication to a patient located in Iowa (eg, providing central fill services for an originating pharmacy located in Iowa or providing professional non-product services only).

The Board's second bill relates to CS and the Iowa Prescription Monitoring Program Advisory Council. The Board annually recommends to the legislature to make permanent the scheduling actions that the Board has taken temporarily via rulemaking, which is in response to scheduling action taken by DEA. The bill also seeks an amendment to the composition and appointment of

the Iowa Prescription Monitoring Program Advisory Council. The Board is proposing to have the council be Board-appointed, remove the minimum number of members, modify the composition of the council, direct the Board to consult with professional organizations and licensing boards for membership, and direct the Board to adopt rules on matters of the council, including terms of appointment and quorum.

The Board will provide updates to its legislative initiatives at its regular open session meetings in March and May.

National Pharmacy Compliance News Now Available!

Visit NABP's website for the latest regulatory updates and news from FDA, USP, NABP, and more.

Read National News

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